Amendments to the Claims:

This listing of claims will replace all prior versions and listing of claims in the application.

Listing of Claims:

Claims 1-161 (canceled)

Claim 162 (new): A method for inducing an antigen-specific immune response in a subject comprising:

a) pretreating an area of the skin of the subject, wherein pretreating comprises applying means for enhancing penetration and/or barrier disruption of the skin; and

b) applying a formulation transcutaneously to the pretreated area to induce an antigen-specific immune response, wherein the formulation comprises:

1) an antigen in an amount effective to induce an antigen-specific immune response;

2) an adjuvant present in an amount effective to enhance the immune response to the antigen; and,

3) a pharmaceutically acceptable carrier;

wherein pretreating enhances the immune response.

Claim 163 (new): The method of claim 162, wherein pretreating comprises applying to the skin a chemical means, a physical means, a mechanical means, a hydration means, or a combination thereof.

Claim 164 (new): The method of claim 162, wherein pretreating comprises applying a chemical to the skin.

Claim 165 (new): The method of claim 164, wherein the chemical is an acetone, a detergent, a depilatory agent, a keratinolytic formulation, or a combination thereof.

Claim 166 (new): The method of claim 162, wherein pretreating comprises applying a device.

Claim 167 (new): The method of claim 166, wherein the device is selected from the group consisting of a propellant device, a device comprising tines, a device comprising microneedles, a device comprising a tine disk, a tape stripping device, a gas powered gun, a swab, an emery board, an abrasive pad, an electroporation device, an ultrasound device, and an iontophoresis device.

Claim 168 (new): The method of claim 166, wherein a patch comprises the device.

Claim 169 (new): The method of claim 162, wherein the antigen is a nucleic acid, carbohydrate, a glycolipid, a glycoprotein, a lipid, a lipoprotein, phospholipid, a polypeptide, a protein, a fusion protein, or chemical conjugate of a combination thereof.

Claim 170 (new): The method of claim 162, wherein the antigen is derived from a pathogen.

Claim 171 (new): The method of claim 170, wherein the pathogen is a virus, a bacterium, a parasite, or a fungus.

Claim 172 (new): The method of claim 171, wherein the virus is an influenza virus or a rabies virus.

Claim 173 (new): The method of claim 172, wherein the antigen is hemagglutinin A.

Claim 174 (new): The method of claim 171, wherein the bacterium is *E. coli* or *Bacillus anthracis*.

Claim 175 (new): The method of claim 174, wherein the antigen is *E. coli* heat-labile enterotoxin (LT).

Claim 176 (new): The method of claim 174, wherein the antigen is a nucleic acid encoding *E. coli* heat-labile enterotoxin (LT).

Claim 177 (new): The method of claim 162, wherein the antigen is a pathogen.

Claim 178 (new): The method of claim 177, wherein the pathogen is a virus, a bacterium, a parasite, or a fungus.

Claim 179 (new): The method of claim 178, wherein the virus is a live virus, an attenuated live virus, an inactivated virus, a detergent treated virus, or a combination thereof.

Claim 180 (new): The method of claim 179, wherein the virus is an influenza virus or a rabies virus.

Claim 181 (new): The method of claim 180, wherein the influenza virus comprises hemagglutinin A.

Claim 182 (new): The method of claim 178, wherein the bacterium is *E coli* or *Bacillus anthracis*.

Claim 183 (new): The method of claim 182, wherein the *E. coli* comprises *E. coli* heat-labile enterotoxin (LT).

Claim 184 (new): The method of claim 162, wherein the antigen is a multivalent antigen.

Claim 185 (new): The method of claim 162, wherein the adjuvant comprises a molecule selected from the group consisting of a bacterial ADP-ribosylating exotoxin (bARE), a binding B

subunit of a bARE, a toxoid of a bARE, a genetically altered bARE, and a genetically detoxified mutant of a bARE.

Claim 186 (new): The method of claim 162, wherein the adjuvant is a nucleic acid encoding a molecule selected from the group consisting of a bacterial ADP-ribosylating exotoxin (bARE), a binding B subunit of a bARE, a toxoid of a bARE, a genetically altered bARE, and a genetically detoxified mutant of a bARE.

Claim 187 (new): The method of claim 162, wherein the antigen and the adjuvant are the same molecule.

Claim 188 (new): The method of claim 187, wherein the molecule is *E. coli* heat-labile enterotoxin (LT).

Claim 189 (new): The method of 162, wherein the formulation is applied using a patch.

Claim 190 (new): The method of claim 162, wherein the adjuvant is selected from the group consisting of nucleic acid, bacterial exotoxin, cytokine, chemokine, lipopolysaccharide, a molecule containing unmethylated CpG motifs, a heat shock protein, a derivative of a heat shock protein, and combinations thereof.

Claim 191 (new): The method of claim 162, wherein the adjuvant is provided as a nucleic acid comprising a sequence encoding the adjuvant.

Claim 192 (new): The method of claim 162, wherein the antigen or adjuvant activates an antigen presenting cell.

Claim 193 (new): The method of claim 192, wherein the antigen presenting cell is a Langerhans cell or a dermal dendritic cell.

Claim 194 (new): A method for inducing an antigen-specific immune response in a subject comprising concurrently,

a) treating an area of the skin of the subject, wherein treating comprises applying means for enhancing penetration and/or barrier disruption of the skin; and

b) applying a formulation transcutaneously to the treated area to induce an antigen-specific immune response, wherein the formulation comprises:

1) an antigen in an amount effective to induce an antigen-specific immune response;

2) an adjuvant present in an amount effective to enhance the immune response to the antigen; and,

3) a pharmaceutically acceptable carrier;

wherein treating enhances the immune response.

Claim 195 (new): The method of claim 194, wherein treating comprises applying to the skin a chemical means, a physical means, a mechanical means, a hydration means, or a combination thereof.

Claim 196 (new): The method of claim 194, wherein treating comprises applying a chemical to the skin.

Claim 197 (new): The method of claim 196, wherein the chemical is an alcohol, an acetone, a detergent, a depilatory agent, a keratinolytic formulation, or a combination thereof.

Claim 198 (new): The method of claim 194, wherein treating comprises applying a device.

Claim 199 (new): The method of claim 198, wherein the device is selected from the group consisting of a propellant device, a device comprising tines, a device comprising microneedles, a device comprising a tine disk, a tape stripping device, a gas powered gun, a swab, an emery board, an abrasive pad, an electroporation device, an ultrasound device, and an

iontophoresis device.

Claim 200 (new): The method of claim 198, wherein a patch comprises the device.

Claim 201 (new): The method of claim 194, wherein the antigen is a nucleic acid, carbohydrate, a glycolipid, a glycoprotein, a lipid, a lipoprotein, phospholipid, a polypeptide, a protein, a fusion protein, or chemical conjugate of a combination thereof.

Claim 202 (new): The method of claim 194, wherein the antigen is derived from a pathogen.

Claim 203 (new): The method of claim 202, wherein the pathogen is a virus, a bacterium, a parasite, or a fungus.

Claim 204 (new): The method of claim 203, wherein the virus is an influenza virus or a rabies virus.

Claim 205 (new): The method of claim 204, wherein the antigen is hemagglutinin A.

Claim 206 (new): The method of claim 205, wherein the bacterium is *E.coli* or *Bacillus anthracis*.

Claim 207 (new): The method of claim 206, wherein the antigen is *E. coli* heat-labile enterotoxin (LT).

Claim 208 (new): The method of claim 206, wherein the antigen is a nucleic acid encoding *E. coli* heat-labile enterotoxin (LT).

Claim 209 (new): The method of claim 194, wherein the antigen is a pathogen.

Claim 210 (new): The method of claim 209, wherein the pathogen is a virus, a bacterium, a parasite, or a fungus.

Claim 211 (new): The method of claim 210, wherein the virus is a live virus, an attenuated live virus, an inactivated virus, a detergent treated virus, or a combination thereof.

Claim 212 (new): The method of claim 211, wherein the virus is an influenza virus or a rabies virus.

Claim 213 (new): The method of claim 212, wherein the influenza virus comprises hemagglutinin.

Claim 214 (new): The method of claim 210, wherein the bacterium is *E. coli* or *Bacillus anthracis*.

Claim 215 (new): The method of claim 214, wherein the *E. coli* comprises *E. coli* heat-labile enterotoxin (LT).

Claim 216 (new): The method of claim 194, wherein the antigen is a multivalent antigen.

Claim 217 (new): The method of claim 194, wherein the adjuvant comprises a molecule selected from the group consisting of a bacterial ADP-ribosylating exotoxin (bARE), a binding B subunit of a bARE, a toxoid of a bARE, a genetically altered bARE, and a genetically detoxified mutant of a bARE.

Claim 218 (new): The method of claim 194, wherein the adjuvant is a nucleic acid encoding a molecule selected from the group consisting of a bacterial ADP-ribosylating exotoxin (bARE), a binding B subunit of a bARE, a toxoid of a bARE, a genetically altered bARE, and a genetically detoxified mutant of a bARE.

Claim 219 (new): The method of claim 194, wherein the antigen and the adjuvant are the same molecule.

Claim 220 (new): The method of claim 219, wherein the molecule is *E. coli* heat-labile enterotoxin (LT).

Claim 221 (new): The method of 194, wherein the formulation is applied using a patch.

Claim 222 (new): The method of claim 194, wherein the adjuvant is selected from the group consisting of nucleic acid, bacterial exotoxin, cytokine, chemokine, lipopolysaccharide, a molecule containing unmethylated CpG motifs, a heat shock protein, a derivative of a heat shock protein, and combinations thereof.

Claim 223 (new): The method of claim 194, wherein the adjuvant is provided as a nucleic acid comprising a sequence encoding the adjuvant.

Claim 224 (new): The method of claim 194, wherein the antigen or adjuvant activates an antigen presenting cell.

Claim 225 (new): The method of claim 224, wherein the antigen presenting cell is a Langerhans cell or a dermal dendritic cell.

Claim 226 (new): A method for inducing an antigen-specific immune response in a subject comprising:

a) delivering parenterally a first formulation comprising an antigen to a subject;

b) treating an area of the skin of the subject, wherein treating comprises applying means for enhancing penetration and/or barrier disruption of the skin to enhance the immune response; and

c) applying transcutaneously a second formulation comprising an adjuvant to the area of the skin, thereby inducing an antigen-specific immune response.

Claim 227 (new): The method of claim 226, wherein treating comprises applying to the skin a chemical means, a physical means, a mechanical means, a hydration means, or a combination thereof.

Claim 228 (new): The method of claim 226, wherein treating comprises applying a chemical to the area of the skin.

Claim 229 (new): The method of claim 228, wherein the chemical is an acetone, a detergent, a depilatory agent, a keratinolytic formulation, or a combination thereof.

Claim 230 (new): The method of claim 226, wherein treating comprises applying a device.

Claim 231 (previously presented): The method of claim 230, wherein the device is selected from the group consisting of a propellant device, a device comprising tines, a device comprising microneedles, a device comprising a tine disk, a tape stripping device, a gas powered gun, a swab, an emery board, an abrasive pad, an electroporation device, an ultrasound device, and an iontophoresis device.

Claim 232 (previously presented): The method of claim 230, wherein a patch comprises the device.

Claim 233 (new): The method of claim 226, wherein the antigen is a nucleic acid, a carbohydrate, a glycolipid, a glycoprotein, a lipid, a lipoprotein, phospholipid, a polypeptide, a protein, a fusion protein, or chemical conjugate of a combination thereof.

Claim 234 (new): The method of claim 226, wherein the antigen is derived from a pathogen.

Claim 235 (new): The method of claim 234, wherein the pathogen is a virus, a bacterium, a parasite, or a fungus.

Claim 236 (new): The method of claim 235, wherein the virus is an influenza virus or a rabies virus.

Claim 237 (new): The method of claim 236, wherein the antigen is hemagglutinin A.

Claim 238 (new): The method of claim 235, wherein the bacterium is *E. coli* or *Bacillus anthracis*.

Claim 239 (new): The method of claim 238, wherein the antigen is *E. coli* heat-labile enterotoxin (LT).

Claim 240 (new): The method of claim 237, wherein the antigen is a nucleic acid encoding *E. coli* heat-labile enterotoxin (LT).

Claim 241 (new): The method of claim 226, wherein the antigen is a pathogen.

Claim 242 (new): The method of claim 241, wherein the pathogen is a virus, a bacterium, a parasite, or a fungus.

Claim 243 (new): The method of claim 242, wherein the virus is a live virus, an attenuated live virus, an inactivated virus, a detergent treated virus, or a combination thereof.

Claim 244 (new): The method of claim 243, wherein the virus is an influenza virus or a rabies virus.

Claim 245 (new): The method of claim 244, wherein the influenza virus comprises hemagglutinin A.

Claim 246 (new): The method of claim 242, wherein the bacterium is *E coli* or *Bacillus anthracis*.

Claim 247 (new): The method of claim 246, wherein the *E. coli* comprises *E. coli* heat-labile enterotoxin (LT).

Claim 248 (new): The method of claim 226, wherein the antigen is a multivalent antigen.

Claim 249 (new): The method of claim 226, wherein the adjuvant comprises a molecule selected from the group consisting of a bacterial ADP-ribosylating exotoxin (bARE), a binding B subunit of a bARE, a toxoid of a bARE, a genetically altered bARE, and a genetically detoxified mutant of a bARE.

Claim 250 (new): The method of claim 226, wherein the adjuvant is a nucleic acid encoding a molecule selected from the group consisting of a bacterial ADP-ribosylating exotoxin (bARE), a binding B subunit of a bARE, a toxoid of a bARE, a genetically altered bARE, and a genetically detoxified mutant of a bARE.

Claim 251 (new): The method of claim 226, wherein the adjuvant is selected from the group consisting of nucleic acid, bacterial exotoxin, cytokine, chemokine, lipopolysaccharide, a molecule containing unmethylated CpG motifs, a heat shock protein, a derivative of a heat shock protein, and combinations thereof.

Claim 252 (new): The method of claim 226, wherein the adjuvant is provided as a nucleic acid comprising a sequence encoding the adjuvant.

Claim 253 (new): The method of claim 226, wherein the antigen or adjuvant activates an antigen presenting cell.

Claim 254 (new): The method of claim 253, wherein the antigen presenting cell is a Langerhans cell or a dermal dendritic cell.

Claim 255 (new): The method of claim 226, wherein the first formulation is administered subcutaneously, intradermally, or intramuscularly.

Claim 256 (new): The method of claim 226, wherein the second formulation is applied using a patch.